AgaMatrix

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510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

NOV 13 2006

The assigned 510(k) number is: [redacted] K062434

1. **Submitter's Name, Address, Telephone Number, Contact Person, and date the summary was prepared.**

Submitter's Name:	AgaMatrix, Inc. 10 Manor Parkway Salem, NH 03079
Contact Person:	Connie Hertel Director Quality & Regulatory Affairs
Telephone:	(603) 328-6000
Fax:	(603) 893-4191
Date the summary prepared:	August 17, 2006

2. **Device Name**

Classification Name:	None [1,2]
Common/Usual Name:	Data Management Software
Proprietary Name:	Zero-Click™ Blood Glucose Management System

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[1] Zero-Click™ Blood Glucose Management System is considered an "unclassified" accessory to a blood glucose test system, Product Code NBW

[2] The regulation for the parent device (blood glucose monitor, Class II) is 21 CFR 862.1345, System Test , Blood Glucose.

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3. Legally Marketed Device to which Substantial Equivalence is Claimed:

Predicate Device	510(k) number
FreeStyle™ Connect Data Management System	k994433

4. Intended Use of the Device

The Zero-Click™ Data Management System is intended for use in the home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the AgaMatrix's Liberty™ Blood Glucose Monitoring System. The Zero-Click™ Data Management System allows users to download Blood glucose reading automatically from the meter to the PC without clicking a button.

5. Device Description

The Zero-Click™ Data Management System is an optional data management software accessory for use with the AgaMatrix's Liberty™ Blood Glucose Monitoring System. The Zero-Click™ Data Management System allows the transfer of data from the AgaMatrix's Liberty™ Blood Glucose meter to a personal computer for enhanced data management capability. The Zero-Click™ Data Management System eliminates the need for manual data logs and provides enhance glucose reading trends and statistics. Using the unique Zero-Click™ USB cable, glucose readings are automatically downloaded from the Liberty™ Meter to a PC without pressing a button.

6. Principle of Operation

The Zero-Click™ Data Management System uploads each blood glucose test result and the date and time of the measurement from the memory of the AgaMatrix Liberty™ Blood Glucose meter through a unique USB cable, automatically without having to click a button.

The Zero-Click™ Data Management System operates in a Microsoft Windows Operating System platform and creates reports allowing the user to display a Variety of graphs and statistics based on user-selectable date intervals and blood glucose target ranges.

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7. Summary of Data Demonstrating Substantial Equivalence

System testing was performed with the Zero-ClickTM Data Management System to ensure the optional accessory is equivalent to a currently marketed device (FreeStyle™ Connect Data Management System). These tests consisted of system, hardware, software, and electrical safety (EMC, EMI, and ESD) and clinical user study which consisted of lay users with diabetes and Health Care Professionals (HCPs) to demonstrate the ease of operating the Zero-Click Data Management Software as intended.

Software verification and validation testing demonstrated that the Zero-Click™ Data Management System meets the performance requirements for the intended use of the optional accessory device and the resultant modification has not affected safety of effectiveness.

8. Conclusions

Software verification and validation testing demonstrates that the Zero-Click™ Data Management System is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Connie Hertel
AgaMatrix, Inc.
10 Manor Parkway
Salem, NH 03079

NOV 13 2006

Re: k062434
Trade/Device Name: AgaMatrix Liberty™ Blood Glucose Monitoring System
AgaMatrix Liberty™ Blood Glucose Monitoring System with an Optimal Accessary the Zero-Click™ Blood Glucose Data Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: October 16, 2006
Received: October 17, 2006

Dear Ms. Hertel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

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Indications For Use

510(k) Number (if known): [redacted] K062434

Device Name: AgaMatrix Liberty™ Blood Glucose Monitoring System

AgaMatrix Liberty™ Blood Glucose Monitoring System:
AgaMatrix Liberty™ Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Blood Glucose Meter:
AgaMatrix Liberty™ Blood Glucose Meter is intended for use with AgaMatrix Liberty™ Blood Glucose Test Strips for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Blood Glucose Test Strips:
AgaMatrix Liberty™ Blood Glucose Test Strips are intended for use with AgaMatrix Liberty™ Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (*in vitro* diagnostic use). It is indicated for use at home (over the counter (OTC)) by persons with diabetes, or in a clinical setting by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

AgaMatrix Liberty™ Control Solution:
AgaMatrix Liberty™ Control Solution is intended for use with the AgaMatrix Liberty™ Meter and AgaMatrix Liberty™ Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription (21 CFR 801 Subpart D)	AND/OR	Over the Counter (21 CFR 801 Subpart C)
X		X

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062434

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Indications For Use

510(k) Number (if known): [redacted] K062434

Device Name: **AgaMatrix Liberty™ Blood Glucose Monitoring System with an Optional Accessary the Zero-Click™ Blood Glucose Data Management Software**

Zero-Click™ Blood Glucose Data Management Software

AgaMatrix Zero-Click™ Blood Glucose Data Management System is intended for use in the home and professional settings to aid people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the AgaMatrix Liberty™ Blood Glucose Monitoring System. The Zero-Click™ Blood Glucose Data Management System allows users to download Blood glucose reading automatically from the meter to the PC without clicking a button.

Prescription X AND/OR Over the Counter X
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Carol C. Benson
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Office of In Vitro Diagnostic Device
Evaluation and Safety

K062434